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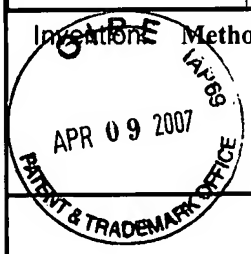
TRANSMITTAL OF APPEAL BRIEF (Large Entity)	Docket No. 11.023011 CIP

In Re Application Of: **Linder**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/618,443	07/11/03	Mummert, Stephanie Kane	38732	1637	4868

Invention: **Methods, Compositions and Apparatuses for Detecting a Target in a Preservative Solution**



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Application No. **10/618,443**	Filing Date **07/11/2003**	Examiner **Mummert, Stephanie Kane**	Customer No. **38732**	Group Art Unit **1637**

Invention: **Methods, Compositions and Apparatuses for Detecting a Target In a Preservative Solution**

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Linder *et al.*	Group Art Unit: 1637
Appl. No.:	10/618,443	Examiner: Mummert, Stephanie
Filed:	July 11, 2003	
For:	METHODS, COMPOSITIONS AND APPARATUSES FOR DETECTING A TARGET IN A PRESERVATIVE SOLUTION	

APPEAL BRIEF

Sir:

This Appeal Brief is filed in response to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed January 6, 2007.

Real Party in Interest.

The real party in interest in this appeal is Cytyc Corporation, Inc., the assignee of the above-referenced patent application.

Related Appeals and Interferences.

There are no related appeals and/or interferences involving this application or its subject matter.

Status of Claims.

Claims 1-23, 26-29, and 36-37 are the subject of this appeal. The claims appear in Appendix A. No other claims are pending. Claims 24-25 and 30-35 have been cancelled.

Status of Amendments.

All of Appellant's amendments have been entered.

Summary of Claimed Subject Matter.

This invention relates to methods, articles and compositions useful in detecting target substances in an alcoholic preservative solution, and for identifying sensors useful for binding to such targets. The methods allow for the simultaneous performance of sufficient fixation of a sample and binding of a detectable sensor to a target of interest in the sample. A summary of the claimed

subject matter defined in independent claims 1 and 28 involved in the appeal may be found paragraphs [0014] to [0018] of the specification as well as Examples 1 and 2 found from paragraphs [0092] to [0106].

Grounds of Rejection to be Reviewed on Appeal.

Whether claim **28** is patentable under 35 U.S.C. § 102(e) over Lorincz *et al.* (U.S. Patent No. 6,969,585);

Whether claims **1-4, 8-12, 14-16, 18-19, and 23-27** are patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723);

Whether claims **20-22** are patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) and in further view of Challberg *et al.* (WO93/10263);

Whether claim **29** is patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Challberg *et al.* (WO93/10263);

Whether claims **5, 7, 29, and 36-37** are patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) and in further view of Hyldig-Nielsen *et al.* (U.S. Patent No. 6,280,946);

Whether claim **6** is patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) and in further view of Kumar *et al.* (Bioorganic & Medicinal Chemistry, 1998, vol. 8, pp. 2219-2222);

Whether claim **10** is patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) and in further view of Bruchez, Jr. *et al.* (Science, 1998, vol. 281, pp. 2013-2016);

Whether claim **13** is patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) and in further view of Ylikoski *et al.* (U.S. Patent No. 5,256,535);

Whether claim **17** is patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) and in further view of Fukasawa *et al.* (Science, 1996, vol. 271, pp. 1744-1747).

Grouping of Claims.

The claims do not stand or fall together. Claim 28 have been rejected under 35 U.S.C. §102(e) as being unpatentable over Lorincz *et al.* (U.S. Patent No. 6,969,585). Claims 1-23, 26, 29, and 36-37 have been rejected under 35 U.S.C. §103(a). Accordingly, the issues surrounding the claims are different, and the claims do not stand or fall together.

ARGUMENT

A. Claim 28 Is Patentable Over Lorincz *et al.*

The Examiner rejected independent claim 28 under 35 U.S.C. § 102(e) as being anticipated by Lorincz *et al.* (U.S. Patent No. 6,969,585).

In the Office Action dated April 26, 2006, the Examiner asserted that the Patent to Lorincz *et al.* teaches a universal collection medium for cell collection which allows for cytology and direct molecular analysis on cells preserved in a sample. The Examiner stated that Lorincz *et al.* teaches "... a method for identifying a sensor which specifically binds to a desired target comprising: a) contacting a sample suspected of containing a target of interest with a detectable sensor, wherein said contacting takes place in a preservative solution comprising as amount of one or more water soluble alcohols effective to preserve such solution against one contaminant (Example 1, where the DNA/RNA protocol was taught, where a DNA biotinylated probe was added directly to samples and incubated at 65°C for hybridization, followed by transfer to a streptavidin coated microplate, followed by chemiluminescent detection; col. 10, where the formulation of the universal collection medium are listed, which comprise an alcoholic preservative solution; see Examples 3-5, where samples are incubated and hybridized in UCM formulations indicated at col. 10); ... " (see page 3 of the Office Action). The Appellants respectfully disagree.

It is the Appellants' position that Lorincz *et al.* does not anticipate independent claim 28. "[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every limitation of the claimed invention, either expressly or inherently, such that a person of

ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Systems, Inc. v. Kent State University, 212 F.3d 1272 (Fed. Cir. 2000). Lorincz *et al.* does not meet this standard. Claim 28 recites a method for identifying a sensor which specifically binds to a desired target, comprising: contacting a sample suspected of containing a target of interest with a detectable sensor, wherein said contacting takes place in a preservative solution comprising an amount of one or more water-soluble alcohols effective to preserve such solution against at least one contaminant and does not contain formamide; and detecting whether said sensor has bound to said target.

As mentioned in the Appellants' response filed July 25, 2006, Example 1 of Lorincz *et al.* states that the assay for nucleic acids follows "... in general principle the method for detecting HIV RNA by the Digene Hybrid Capture HIV Test, described in WO 93/10263" (see column 10, last paragraph). The method taught in WO 93/10263 is exemplified by Example 1 of the application. In Example 1, the method clearly requires that "... after hydrolysis, a 150ul aliquot was removed from the sample tube and added to 50ul of a probe diluent containing Probe A, B, or C." (emphasis added) (see page 26, lines 29-31). Thus, in Lorincz *et al.*, the contacting of a target of interest with a detectable sensor does not take in a preservative solution as specified by the current claims. Since the method taught in Lorincz *et al.* specifically teaches the binding of the sensor to the target in a completely different solution than a preservative solution, Lorincz *et al.* cannot anticipate Claim 28.

In the final Office Action dated October 13, 2006, the Examiner disagreed with the Appellants' reading and interpretation of the method of analysis taught by Lorincz *et al.* The Examiner argued that while the protocol of Lorincz *et al.* does require that an aliquot of the sample

is removed from the original tube/container and added to a probe diluent, there appears to be "...no indication that the original preservative solution in which the sample was maintained (ViraPap™ in this instance) was no longer present in the sample following the hydrolysis step. Therefore presuming that the method taught by Lorincz *et al.* actually follows the specific method steps disclosed in the WO 93/10263 document, the contacting does take place in a composition comprising the preservative solution." (page 18; Final Office Action). The Appellants respectfully disagree with the Examiner.

The Examiner has not pointed out with clarity and specificity where every limitation of the claimed invention, either expressly or inherently, can be found within the four corners of Lorincz *et al.* According to the Federal Circuit, anticipation requires the disclosure of "... a single prior art reference of each element of the claim under construction." (W.L. Gore & Assocs. vs. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983)). It is not enough that the reference disclose all of the elements in isolation. The Federal Circuit has stated that a prior art reference must disclose each of the elements of a claimed invention "arranged as in the claim". (see Lindemann Maschinenfabrik GmbH vs. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 193 (Fed. Cir. 1984). The prior art reference Lorincz *et al.* does not disclose each of the elements of the claimed invention nor arranged as in the present claims.

The claim 28 requires the unique step of contacting a sample with a detectable sensor in solution, specifically "...wherein said contacting takes place in a preservative solution..." This step clearly requires that the contacting of the sample with a sensor takes place <u>in a preservative solution</u>. Not only does claim 28 require the contacting of a sample with a detectable sensor in preservative

solution, but the preservative solution must specifically be comprised of at least "...an amount of one or more water-soluble alcohols effective to preserve such solution against at least one contaminant..." The Examiner has not pointed out with clarity and specificity where the limitation of contacting a sample with a detectable sensor in preservative solution, either expressly or inherently, can be found within the four corners of Lorincz *et al.*

In the Final Office Action, the Examiner argued that the disclosure of Lorincz *et al.* (col. 10, lines 58-61) "...indicates that the contacting does, indeed, occur in the presence of the preservative solution disclosed by Lorincz." (emphasis added) (Page 19 of Final Office Action). The Appellants disagree that contacting a sample with a sensor in the presence of a preservative solution is the same as contacting a sample with a sensor in a preservative solution.

All Examples described in Lorincz *et al.* and cited by the Examiner require the manipulation of preserved cells outside of the original solution in which the cells are collected. Whether the manipulation takes place on a slide or in a separate well of a microplate, the cells are no longer in the original collection solution and no further hybridizations, bindings or other experimental protocols takes place in that solution. The Examiner has failed to point out with clarity and specificity where the specific limitation of the claimed invention of contacting of a sample with a sensor in a preservative solution, either expressly or inherently, can be found within the four corners of Lorincz *et al.* Since the method taught in Lorincz *et al.* does not teach or suggest contacting a sample with a detectable sensor in a preservative solution comprising an amount of one or more water-soluble alcohols effective to preserve such solution against at least one contaminant and does not contain formamide, Lorincz *et al.* cannot anticipate Claim 28.

For these reasons, the Appellants respectfully requests the withdrawal of the rejection of claim 28 under 35 U.S.C. §102(e) in view of the Lorincz *et al.*

B. Claims 1-4, 8-12, 14-16, 18-19 And 23-27 Are Patentable Over Lorincz *et al.* in View of Shah *et al.*

Claims 1-4, 8-12, 14-16, 18-19, and 23-27 were rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) as applied to claim 28 above in further view of Shah *et al.* (U.S. Patent No. 6,165,723).

In the Office Action dated April 26, 2006, the Examiner asserted that the Patent to Lorincz *et al.* teaches a universal collection medium for cell collection which allows for cytology and direct molecular analysis on cells preserved in a sample. With regard to claim 1, the Examiner argued that Lorincz *et al.* teaches a method of "... contacting the sample with the sensor in the alcoholic preservative solution under conditions in which the sensor can bind to the target, if present (Example 1, where the DNA/RNA protocol was taught, where a DNA biotinylated probe was added directly to samples and incubated at 65°C for hybridization, followed by transfer to a streptavidin coated microplate, followed by chemiluminescent detection); ... " (see page 4 of the Office Action). The Appellants respectfully disagree.

As noted in M.P.E.P. § 2143.03, to establish the obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. Independent claim 1 recites an assay method comprising: providing a sample that is suspected of containing a target; providing a sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide,

said sensor conjugated to a chromophore; contacting the sample with the sensor in the alcoholic preservative solution that does not contain formamide under conditions in which the sensor can bind to the target, if present; applying a light source to the solution that can excite the chromophore; and detecting whether light is emitted from the target. As mentioned previously, Lorincz *et al.* does not teach or suggest contacting a sample with a sensor in an alcoholic preservative solution that does not contain formamide under conditions in which the sensor can bind to the target. This deficiency cannot be overcome by Shah *et al.*

Shah *et al.* teaches an *in situ* hybridization method for the detection of target nucleic acids. There is no suggestion or teaching in Shah *et al.* of detecting target nucleic acids in a preservative solution. Thus Shah *et al.* does not teach or suggest all of the limitations of claim 1.

The Examiner has not pointed with specificity to any teaching or suggestion in Lorincz *et al.* or Shah *et al.*, either alone or in combination that recites all the limitations of claim 1. Accordingly, claim 1 and those claims which depend from claim 1 (i.e., 2-4, 8-12, 14-16, 18-19, and 23-27) cannot be obvious in light of Lorincz *et al.* or Shah *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejections of claims 1-4, 8-12, 14-16, 18-19, and 23-27 under 35 U.S.C. §103(a).

C. Dependent Claims 20-22 Are Patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* in further view of Shah *et al.* and in further view of Challberg *et al.*

Dependent claims 20-22 were rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S.

Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) as applied to claims 1-4, 8-12, 14-16, 18-19 and 23-27 above, and in further view of Challberg *et al.* (WO93/10263).

In the Office Action dated April 26, 2006, the Examiner asserted that Lorincz *et al.* in view of Stahl *et al.* teaches all the limitations of claims 1-4, 8-12, 14-16, 18-19 and 23-27 as recited in the rejection above.

As mentioned previously, the Examiner has not pointed with specificity to any teaching or suggestion in Lorincz *et al.* or Shah *et al.*, either alone or in combination that recites all the limitations of claim 1. This deficiency cannot be overcome by Challberg *et al.* Challberg *et al.* teaches a non-radioactive hybridization assay. There is no suggestion or teaching in Challberg *et al.* of detecting target nucleic acids in a preservative solution. Thus Challberg *et al.* does not teach or suggest all of the limitations of claim 1. Accordingly, claim 1 and those claims which depend from claim 1 (i.e., 20-22) cannot be obvious in light of Lorincz *et al.* or Shah *et al.* or Challberg *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejections of claims 20-22 under 35 U.S.C. §103(a).

D. Dependent Claim 29 Is Patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* in further view of Challberg *et al.*

Dependent claim 29 was rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) as applied to claim 28 above, and in further view of Challberg *et al.* (WO93/10263);

In the Office Action dated April 26, 2006, the Examiner asserted that Lorincz *et al.* teaches a universal collection medium for cell collection which allows for cytological and direct molecular

analysis on cells in a single sample.

As mentioned previously, the Examiner has not pointed with specificity to any teaching or suggestion in Lorincz *et al.* that recites all the limitations of claim 28. This deficiency cannot be overcome by Challberg *et al.* Challberg *et al.* teaches a non-radioactive hybridization assay. There is no suggestion or teaching in Challberg *et al.* of detecting target nucleic acids in a preservative solution. Thus Challberg *et al.* does not teach or suggest all of the limitations of claim 28.

Accordingly, claim 28 and those claims which depend from claim 1 (i.e., 29) cannot be obvious in light of Lorincz *et al.* or Challberg *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejection of claim 29 under 35 U.S.C. §103(a).

E. Dependent Claims 5, 7, 29, and 36-37 Are Patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* in further view of Shah *et al.* and in further view of Hyldig-Nielsen *et al.*

Dependent claims 5, 7, 29, and 36-37 were rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) as applied to claims 1-4, 8-12, 14-16, 18-19 and 23-27 above, and in further view of Hyldig-Nielsen *et al.* (U.S. Patent No. 6,280,946).

In the Office Action dated April 26, 2006, the Examiner asserted that Lorincz *et al.* in view of Stahl *et al.* teaches all the limitations of claims 1-4, 8-12, 14-16, 18-19 and 23-27 as recited in the rejection above.

As mentioned previously, the Examiner has not pointed with specificity to any teaching or suggestion in Lorincz *et al.* with Shah *et al.* either alone or in combination that recites all the limitations of independent claim 1 or independent claim 28. This deficiency cannot be overcome by Hyldig-Nielsen *et al.* Hyldig-Nielsen *et al.* teaches the use of PNA probes. There is no suggestion or teaching in Hyldig-Nielsen *et al.* of detecting target nucleic acids in a preservative solution. Thus Hyldig-Nielsen *et al.* does not teach or suggest all of the limitations of claim 1 or claim 28.

Accordingly, claims 1 and 28 and those claims which depend from claims 1 and 28 (i.e., 5, 7, 29, and 36-37) cannot be obvious in light of Lorincz *et al.* or Shah *et al.* or Hyldig-Nielsen *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejections of claims 5, 7, 29, and 36-37 under 35 U.S.C. §103(a).

F. Dependent Claim 6 Is Patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* in further view of Shah *et al.* and in further view of Kumar *et al.*

Dependent claim 6 was rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) as applied to claims 1-4, 8-12, 14-16, 18-19 and 23-27 above, and in further view of Kumar *et al.* (Bioorganic & Medicinal Chemistry, 1998, vol. 8, pp. 2219-2222).

In the Office Action dated April 26, 2006, the Examiner asserted that Lorincz *et al.* in view of Stahl *et al.* teaches all the limitations of claims 1-4, 8-12, 14-16, 18-19 and 23-27 as recited in the rejection above.

As mentioned previously, the Examiner has not pointed with specificity to any teaching or suggestion in Lorincz *et al.* with Shah *et al.* either alone or in combination that recites all the limitations of claim 1. This deficiency cannot be overcome by Kumar *et al.* Kumar *et al.* teaches locked nucleic acids of phosphorothioates. There is no suggestion or teaching in Kumar *et al.* of detecting target nucleic acids in a preservative solution. Thus Kumar *et al.* does not teach or suggest all of the limitations of claim 1.

Accordingly, claim 1 and those claims which depend from claims 1 (i.e., claim 6) cannot be obvious in light of Lorincz *et al.* or Shah *et al.* or Kumar *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejection of claim 6 under 35 U.S.C. §103(a).

G. Dependent Claim 10 Is Patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* in further view of Shah *et al.* and in further view of Bruchez, Jr. *et al.*

Dependent claim 10 was rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) as applied to claims 1-4, 8-12, 14-16, 18-19 and 23-27 above, and in further view of Bruchez, Jr. *et al.* (U.S. Patent No. 6,280,946). In the Office Action dated April 26, 2006, the Examiner asserted that Lorincz *et al.* in view of Stahl *et al.* teaches all the limitations of claims 1-4, 8-12, 14-16, 18-19 and 23-27 as recited in the rejection above.

As mentioned previously, the Examiner has not pointed with specificity to any teaching or

suggestion in Lorincz *et al.* with Shah *et al.* either alone or in combination that recites all the limitations of claim 1. This deficiency cannot be overcome by Kumar *et al.* Kumar *et al.* teaches locked nucleic acids of phosphorothioates. There is no suggestion or teaching in Kumar *et al.* of detecting target nucleic acids in a preservative solution. Thus Kumar *et al.* does not teach or suggest all of the limitations of claim 1.

Accordingly, claim 1 and those claims which depend from claims 1 (i.e., claim 6) cannot be obvious in light of Lorincz *et al.* or Shah *et al.* or Kumar *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejection of claim 6 under 35 U.S.C. §103(a).

H. Dependent Claim 13 Is Patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* in further view of Shah *et al.* and in further view of Ylikoski *et al.*

Dependent claim 13 was rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) as applied to claims 1-4, 8-12, 14-16, 18-19 and 23-27 above, and in further view of Ylikoski *et al.* (U.S. Patent No. 5,256,535).

In the Office Action dated April 26, 2006, the Examiner asserted that Lorincz *et al.* in view of Stahl *et al.* teaches all the limitations of claims 1-4, 8-12, 14-16, 18-19 and 23-27 as recited in the rejection above.

As mentioned previously, the Examiner has not pointed with specificity to any teaching or suggestion in Lorincz *et al.* with Shah *et al.* either alone or in combination that recites all the limitations of claim 1. This deficiency cannot be overcome by Ylikoski *et al.* Ylikoski *et al.* teaches a

hybridization assay. There is no suggestion or teaching in Ylikoski *et al.* of detecting target nucleic acids in a preservative solution. Thus Ylikoski *et al.* does not teach or suggest all of the limitations of claim 1.

Accordingly, claim 1 and those claims which depend from claims 1 (i.e., claim 13) cannot be obvious in light of Lorincz *et al.* or Shah *et al.* or Ylikoski *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejection of claim 13 under 35 U.S.C. §103(a).

I. Dependent Claim 17 Is Patentable under 35 U.S.C. § 103(a) over Lorincz *et al.* in further view of Shah *et al.* and in further view of Fukasawa *et al.*

Dependent claim 17 was rejected under 35 U.S.C. § 103(a) over Lorincz *et al.* (U.S. Patent No. 6,969,585) in further view of Shah *et al.* (U.S. Patent No. 6,165,723) as applied to claims 1-4, 8-12, 14-16, 18-19 and 23-27 above and in further view of Fukasawa *et al.* (Science, 1996, vol. 271, pp. 1744-1747). In the Office Action dated April 26, 2006, the Examiner asserted that Lorincz *et al.* in view of Stahl *et al.* teaches all the limitations of claims 1-4, 8-12, 14-16, 18-19 and 23-27 as recited in the rejection above.

As mentioned previously, the Examiner has not pointed with specificity to any teaching or suggestion in Lorincz *et al.* with Shah *et al.* either alone or in combination that recites all the limitations of claim 1. This deficiency cannot be overcome by Fukasawa *et al.* Fukasawa *et al.* teaches abnormal centrosome amplification in the absence of p53. There is no suggestion or teaching in Fukasawa *et al.* of detecting target nucleic acids in a preservative solution. Thus

Fukasawa *et al.* does not teach or suggest all of the limitations of claim 1.

Accordingly, claim 1 and those claims which depend from claims 1 (i.e., claim 17) cannot be obvious in light of Lorincz *et al.* or Shah *et al.* or Fukasawa *et al.*

For all the reasons listed above, the Appellant respectfully requests the withdrawal of the rejection of claim 17 under 35 U.S.C. §103(a).

CONCLUSION

In light of the above arguments, Appellant respectfully submits that the cited references do not anticipate nor render obvious the claimed invention. More specifically, Appellants' claims recite novel physical features which patentably distinguish over any and all references under 35 U.S.C. §§ 102 and 103. As a result, a decision by the Board of Patent Appeals and Interferences reversing the Examiner and directing allowance of the pending claims in the subject application is respectfully solicited.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

1. An assay method comprising: providing a sample that is suspected of containing a target; providing a sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide, said sensor conjugated to a chromophore; contacting the sample with the sensor in the alcoholic preservative solution that does not contain formamide under conditions in which the sensor can bind to the target, if present; applying a light source to the solution that can excite the chromophore; and detecting whether light is emitted from the target.

2. The method of claim 1, wherein the sample is selected from the group consisting of blood; urine; semen; milk; sputum; mucus; plueral fluid; pelvic fluid; sinovial fluid; ascites fluid; a body cavity wash; eye brushing; skin scrapings; a buccal swab; a vaginal swab; a pap smear; a rectal swab; an aspirate; a needle biopsy; a section of tissue; plasma; serum; spinal fluid; lymph fluid; an external secretion of the skin, respiratory, intestinal, or genitourinary tract; tears; saliva; a tumor; an organ; a microbial culture; and an in vitro cell culture constituent.

3. The method of claim 1, wherein the sensor comprises an aptamer.

4. The method of claim 1, wherein the sensor comprises a polynucleotide.

5. The method of claim 1, wherein the sensor comprises a peptide nucleic acid.

6. The method of claim 1, wherein the sensor comprises a locked nucleic acid.

7. The method of claim 1, wherein the sample is contacted with a plurality of different sensors, each of said plurality comprising a corresponding different detectable label, wherein each of said plurality can selectively bind to a corresponding different target.

8. The method of claim 1, wherein the chromophore is a fluorophore.

9. The method of claim 8, wherein the fluorophore is selected from a semiconductor nanocrystal, a fluorescent dye, and a lanthanide chelate.

10. The method of claim 9, wherein the fluorophore is a semiconductor nanocrystal.

11. The method of claim 9, wherein the fluorophore is a fluorescent dye.

12. The method of claim 11, wherein the fluorescent dye is fluorescein.

13. The method of claim 9, wherein the fluorophore is a lanthanide chelate.

14. The method of claim 1, wherein the target is DNA.

15. The method of claim 1, wherein the target is RNA.

16. The method of claim 1, wherein said sample is a cellular fraction.

17. The method of claim 1, wherein the target is centrosomal.

18. The method of claim 1, wherein said target is a pathological organism.

19. The method of claim 1, wherein said target is a virus.

20. The method of claim 1, further comprising comparing a result from said detecting to a result obtained from a control sample.

21. The method of claim 20, where the control sample is a positive control.

22. The method of claim 20, where the control sample is a negative control.

23. The method of claim 1, further comprising washing said sample prior to said detecting.

26. The method of claim 1, wherein the method is automated.

27. The method of claim 1, wherein the method is performed manually.

28. A method for identifying a sensor which specifically binds to a desired target, comprising: contacting a sample suspected of containing a target of interest with a detectable sensor, wherein said contacting takes place in a preservative solution comprising an amount of one or more water-soluble alcohols effective to preserve such solution against at least one contaminant and does not contain formamide; and detecting whether said sensor has bound to said target.

29. The method of claim 28, wherein the method is performed on a plurality of candidate sensors.

36. The method of claim 1, wherein said target is a bacterium or component or product thereof.

37. The method of claim 1, wherein said target is a yeast or component or product thereof.

APPENDIX B: EVIDENCE

NONE

APPENDIX C: RELATED PROCEEDINGS

NONE